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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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H. Garrett Wada

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EXAMINER

SALMON, KATHERINE D

ART UNIT

PAPER NUMBER

1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/821,657	<b>Applicant(s)</b> WADA ET AL.	
	<b>Examiner</b> KATHERINE SALMON	<b>Art Unit</b> 1634	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: See Continuation Sheet.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See continuation sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Sarae Bausch/  
 Primary Examiner, Art Unit 1634

Continuation of 7: Claims Rejected 1,3-4,8-14,16-27,29,31-32,35,37-39,41-44,51,53,55-58,60-75,78-79,84,86,88-89,91-93,95-96,98-120

Continuation of 3A: NOTE: The proposed amendments to the claims will not be entered as the proposed amendments require further search and consideration. The proposed limitation requiring "electrophoretically separating in the presence of a third polyanion the complex from any unbound conjugate" with the dependent claims of Claim 1 is a new limitation which would require further search and consideration under 35 USC 112/2<sup>nd</sup> and 35 USC 103. For instance the limitation of "electrophoretically separating in the presence of a third polyanion the complex from any unbound conjugate" wherein the third polyanion is heparin sulfate (claim 8) would require further search and consideration.

Continuation of 11: NOTE: The reply asserts that although the term "third" is added by amendment to the claims, the "third polyanion" refers to the polyanion associated with the separating step, which was already recited in the claims (p. 20 3<sup>rd</sup> paragraph).

This argument has been fully reviewed but has not been found persuasive.

Claim 1 as previously amended was drawn to electrophoretically separating the complex and any unbound conjugate, however, Claim 1 did not require separating in the presence of a third polyanion. Therefore claims dependent to Claim 1 did not encompass such a limitation. As stated above, the proposed amendment to the claims is not entered as it would require further search and consideration.

The arguments presented on p. 22 last paragraph, 23 1<sup>st</sup> and last paragraph, p. 24 4<sup>th</sup> paragraph, p. 25 2<sup>nd</sup> and 4<sup>th</sup> paragraph, p. 26 3<sup>rd</sup> and last paragraph, p. 35 4<sup>th</sup> paragraph, and p. 36 1<sup>st</sup> and 3<sup>rd</sup> paragraph are moot as they are drawn to amendments to the claims which are not entered.

The reply traverses the rejection of Claims 93 and 119-120 under 35 USC 103(a) as obvious over Chen in view of Xu and Janssens and further in view of Kaniansky (p. 27 1<sup>st</sup> paragraph). With regard to Janssens reference the applicants assert that Janssens does not teach that the third polyanion reduces interference with separating the complex (p. 29 last paragraph). The reply asserts that it is not clear why a shorter migration time would reduce the degree of interference between an analyte and the capillary column (p. 29 last paragraph). The reply asserts that Janssens et al is concerned with stabilizing electroosmotic flow and not with reducing interference (p. 29 last paragraph). The reply asserts that the claimed invention is concerned with reducing interference from sample constituents (e.g. noise constituents) which derive from the sample and not interference due to the separation channel walls (p. 30 1<sup>st</sup> paragraph). The reply asserts that the amendment of the claim to recite that "the first, second, and third polyanions reduce interference with separating the complex" limits the claim to such an interference (p. 30 1<sup>st</sup> paragraph).

This argument has been fully reviewed but has not been found persuasive.

It is noted that the proposed claim amendments have not been entered and as such Claim 93 is not limited to "the first, second, and third polyanions reduce interference with separating the complex", but rather that the first, second, and third polyanions reduce interference with separating the complex. In this example, the shorter migration time would require that the complex be present in the capillary column for a shorter period of time and therefore there would be a shorter time prior for the complex to miscomplex with the components in the column.

The reply asserts that Janssens does not disclose the separation of complexes but only noncomplexed analytes (p. 30 2<sup>nd</sup> paragraph). The reply asserts that as such that Janssens does not teach or suggest the separation of complexed analytes species nor the use of polyanions to reduce interference with separating such analytes as Claim 1 has been amended (p. 30 last two paragraphs).

This argument has been fully reviewed but has not been found persuasive.

It is the combination of the art which teach the method. Herein in the instant case Chen et al teaches the method of separating the complexed analyte.

The applicant argues that Kaniansky et al. does not teach a second polyanion as MHEC is not a polyanion (p. 31 2<sup>nd</sup> full paragraph). The reply asserts that the polyanionic cellulose compound evidenced by Huth is a metal carboxy methylhydroxethylcellulose and this is different than the MHEC of Kaniansky (p. 31). The applicant provides support for the structural differences on p. 31-p. 32 of the reply. The reply asserts that Kaniansky uses MHEC to suppress electroosmotic flow, however does not teach a concentrating step in the presence of a polyanion (p. 32 last two paragraph-p. 33 1st two paragraph).

This argument has been fully reviewed but has not been found persuasive.

Although it is acknowledge the MHEC in itself cannot be considered a polyanion, Kaniansky et al. does teach using MHEC in combination with a polyanion (table 3). Specifically Kaniansky et al. teaches carrier anions, leading anions, and terminating anions. Therefore the solution of Kaniansky et al would comprise the polyanion for which the pending claims are limited. As stated in the final rejection it would be obvious to use the ITP and the components in the ITP (e.g. the solution containing polyanions), because Kaniansky et al. teaches that these ITP solutions pretreat quantified test analytes (abstract).

The reply asserts that the teaching of Janssens and Kaniansky are at odds with one another and would lead one of skill in the art away from combining them with each other (p. 33 last paragraph). The reply asserts that Janssens teaches that the addition of both a polycation and a polyanion results in a stable more reproducible EOF, whereas Kaniansky teaches the use of a neutral polymer for suppressing EOF (p. 34 1<sup>st</sup> paragraph). The reply asserts that there the motivated provided are contradictory as one seeks to stabiles while the other teaches to suppress (p. 34 1<sup>st</sup> paragraph). The reply asserts that further neither Janssens nor Kaniansky teach adding a second or third polyanion to reduce interference with separating the analytes due to noise constituents in a sample (p. 34 last paragraph).

This argument has been fully reviewed but has not been found persuasive.

The reply is arguing that Kaniansky et al. and Janssens et al. would not be combined as they are contradictory. However, as stated above although MHEC is a neutral polymer, the solution of Kaniansky et al. does comprise polyanions. Further it is agreed that Kaniansky et al teaches that these solution reduce EOF. Janssens et al. also teaches that there are additives added to decrease or to suppress the electroosmotic mobility (column 5 lines 1-5). However, Janssens et al. teaches that the instant capillaries use the same buffers as conventional capillary but the etching of the tube allows for a direct stabilization of the EOF (column 7 lines 20-35 and Table 2). Janssens et al. teaches that using this method a higher degree of separation can be achieved through a single run (column 7 lines 45-55). Therefore Janssens et al. does not teach away from the teachings of Kaniansky et al, but rather, using known buffers solutions which

comprise a polyanion or a mixture of polyanions (column 8 lines 40-50) stabilize EOF using a capillary initiator. As such the ordinary artisan would be motivated to use the solution of Kaniansky et al. in the method of Janssens et al. in order to stabilize the EOF and increase separation. Further it is noted that the proposed amendments to the claims are not entered and therefore the claims as pending do not require "adding a second or third polyanion to reduce interference with separating the analytes due to noise constituents in the sample".